In Reply to USPTO Correspondence of December 24, 2008

Attorney Docket No. 0262-061920

## **REMARKS**

The Office Action of December 24, 2008 has been reviewed and the Examiner's comments carefully considered. Claims 21-30 are pending in this application. Claim 22 is cancelled and claim 30 has been amended herewith in accordance with the originally filed specification. No new matter has been added. Accordingly, claims 21 and 23-30 remain in this application and claims 21 and 30 are in independent form.

In view of the foregoing amendments, Applicants believe that the asserted rejections should be withdrawn, and that claims 21 and 23-30 are in condition for allowance.

## 35 U.S.C. §112, Second Paragraph, Rejections

Initially, claim 22 stands rejected under 35 U.S.C. §112, second paragraph, for asserted indefiniteness as the Examiner indicates that "up to about" is not defined by the claim. Claim 22 is cancelled herewith. As such, this rejection is now moot and should be withdrawn.

Claim 30 also stands rejected under 35 U.S.C. §112, second paragraph, for asserted indefiniteness for failing to point out and distinctly claim the subject matter which is regarded as the invention. The Examiner asserts that this claim is a product-by-process claim. However, this claim is merely a process claim. To further clarify that claim 30 is a process claim, the language of claim 21 has been incorporated into claim 30 and the dependency of claim 30 from claim 21 is removed herewith. Further, the language of claim 30 has been amended to clarify that only the oil component of the egg is separated from the whole egg or egg yolk and subsequently replaced with the fat or oil component recited therein. Support for this amendment is found at least at page 6, lines 1-9, lines 12-14, and lines 26-28; page 7, lines 31-32; and page 8, lines 7-8 of the originally filed specification. In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection.

## 35 U.S.C. §102 Rejections

Claims 21 and 23-30 stand rejected under 35 U.S.C. §102(b) for asserted anticipation by WO 99/33355 to Sawatzki et al. (hereinafter "Sawatzki"). Further, claims 21 and 23-30 stand rejected under 35 U.S.C. §102(b) for asserted anticipation by EP 0775449 to Akimoto et al. (hereinafter "Akimoto").

The present invention is based on the unexpected finding that the claimed solid fat products, based on whole egg or egg yolk, exhibit an improved oxidation stability

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and bioavailability of bioactive, long-chain polyunsaturated fatty acids (bioactive LC-PUFAs) with at least 20 carbon atoms (see page 2, lines 15-25 and page 3, lines 16-21 of the application as filed). The advantages of the invention can only be achieved when the endogenously present phospholipids of the whole egg or egg yolk are not removed, but retained during manufacturing of the solid fat products.

Whole egg or egg yolk contain a lipid component which consists of a neutral fraction, predominantly consisting of triglycerides and accounting for about 56-64% of the lipid content, and a polar fraction, mainly consisting of phospholipids accounting for about 21-31% of the lipid content. The enrichment of hen eggs with LC-PUFAs by supplementing layer feed with LC-PUFAs containing feed ingredients, however, was found to only allow the production of eggs having a limited, and for many applications, insufficient increase in bioactive LC-PUFAs.

The observed, unexpected, and beneficial effects associated with the solid fat products of the invention are based on the fact that <u>only</u> the triglyceride component (egg oil) is specifically removed and replaced by fats or oils having the desired LC-PUFA pattern, rather than by delipidating the whole egg or egg yolk, *i.e.*, removing all lipid components, as is commonly practiced in the prior art. In other words, only the neutral fraction of the endogenously present lipid component is removed from the whole egg or egg yolk (see page 6, lines 1-9, lines 12-14, and lines 26-28; page 7, lines 31-32; and page 8, lines 7-8 of the application as filed).

Sawatzki has the goal of providing a dietetic or a pharmaceutical product having a balanced ratio of polyunsaturated fatty acids suited for administration to patients suffering from various diseases (see page 3, lines 13-19). Sawatzki solves this problem by incorporating a fat blend with a specific ratio of gamma-linolenic acid (GLA), eicosapentaenoic acid (EPA), and stearidonic acid (SA) into a dietetic or a pharmaceutical product, for example, a liquid enteral food, a fat emulsion, or a reconstitutable food in powder form (see abstract and page 11, lines 1-19).

The fat blend employed by Sawatzki is an oil, fat, and/or lecithin-based fat blend containing polyunsaturated fatty acids, wherein the lecithin used for preparing the fat blend may be lecithin from egg yolk (see abstract and page 7, lines 24-26). More specifically, the fat blend contains gamma-linolenic acid (GLA;  $18:3(\omega-6)$ ), stearidonic acid (SA;  $18:4(\omega-3)$ ), and eicosapentaenoic acid (EPA;  $20:3(\omega-3)$ ), wherein these three fatty acids

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together make up 10 to 500 mg/g of total fatty acids in the fat blend. In addition, the GLA and EPA each represent 20 to 50 wt.%, and the SA represents 15 to 50 wt.% of the sum of these three fatty acids.

In view of the above, it is submitted that Sawatzki fails to teach how to address the problem solved by the present invention, *i.e.*, how to increase the oxidation stability and bioavailability of bioactive LC-PUFAs with at least 20 carbon atoms, and Sawatzki discloses neither a solid fat product <u>based on whole egg or egg yolk</u>, nor a product having a content <u>of more than 5 wt.%</u> of LC-PUFAs with at least 20 carbon atoms based on the total fatty acid content.

Akimoto discloses domestic fowl eggs having a high content of arachidonic acid and optionally docosahexaenoic acid, as well as a process for the production thereof comprising feeding egg-laying domestic fowls ω6 highly unsaturated fatty adds and optionally ω3 highly unsaturated fatty acids (see abstract). Furthermore, Akimoto describes the complete extraction of lipids, *i.e.*, phospholipids, triglycerides (egg oil) and fatty acids, from domestic fowl eggs enriched in arachidonic acid and optionally docosahexaenoic acid by a lipid extraction method (see page 5, line 52 to page 6, line 2). The thus obtained lipid preparation can be used as a supplement for a food product, such as a powdered milk formula for premature infants (see page 6, lines 16 to 36).

However, Akimoto fails to disclose or suggest a <u>solid</u> fat product <u>based on</u> whole egg or egg yolk with a high content of <u>more than 5 wt.%</u> of LC-PUFAs with at least 20 carbon atoms. Furthermore, Akimoto fails to teach or suggest a method wherein only the egg oil is separated from the whole egg or egg yolk and is then replaced by bioactive LC-PUFAs. Moreover, Akimoto neither discloses nor renders obvious the use of phospholipids originating from whole egg or egg yolk to improve oxidation stability or bioavailability of added bioactive LC-PUFAs.

It should be noted that the Examiner's statement at point 6(c) of the Office Action that "the desirable oil containing highly unsaturated fatty acid contains at least 20% arachidonic acid with respect to total fatty acid (see page 4, lines 31-33)" of Akimoto refers to an oil that may be used to supplement the feed of the domestic fowls (see page 4, lines 28-33). Thus, this passage fails to disclose a solid fat product based on whole egg or egg yolk containing LC-PUFAs with 20 or more carbon atoms in an amount of more than 5 wt.% of the total fatty acid content.

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Accordingly, Applicants respectfully assert that the subject matter of pending independent claims 21 and 30 is novel and non-obvious in view of Sawatzki and Akimoto. Claims 23-29, which depend directly from, and add further limitations to claim 21, are novel and non-obvious in view of Sawatzki and Akimoto.

## **CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that all of pending claims 21 and 23-30 in the present application are distinguishable from the cited prior art. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

Respectfully submitted,

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